From Protecting Texts to Protecting Objects in Biotechnology and Software

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From protecting texts to protecting objects in biotechnology and software.

A tale of changes of ontological assumptions in intellectual property protection[*][†]

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[†] All three authors dedicate this paper to Chantal Ducos.

Abstract

Both software and agricultural inventions have recently become patentable. Previously, software was protected by copyright, while agricultural inventions were protected by plant breeder's rights. Here we argue that legislation on intellectual property is shaped by ontological considerations (i.e. ideas about the object to be protected), and we propose that the introduction of patenting in software and biotechnology marks a change from protecting a *text* to protecting an *object*. However, this change rests on outdated assumptions about relationship between structures and functions in both fields. Such an ontological perspective gives us a deeper understanding of recent transformations in intellectual property regimes.

Keywords: Intellectual Property; Patents; Copyright; Software; Biotechnology; Ontology

1. Introduction

Several fundamental changes have affected the intellectual property landscape in recent decades. Two of them have drastically changed the nature of protection, introducing the patentability of biotechnological inventions and of software. We propose that these changes, although driven by specific circumstances and realized through complex legislative paths, share a common element: they change the protection of intellectual property from protecting the (material or immaterial) entity as if it were a text to protecting the same entity as if it were an object. We see this change in new plant varieties (once mainly protected through plant breeder's rights) and software (traditionally protected through copyright). As exemplified by copyright, the *protection of a text* is assigned to the *text as a whole*; it does not cover individual elements such as phrases or words and therefore it is open to continual improvement by a large community of users-producers. In an analogous manner, plant breeder's rights protect the organism as a whole, and do not require knowledge of the genetic make-up of the plant. The *protection of an object*, in contrast, is based on the model of mechanical inventions that assumes a narrow relationship between the structure of an object and the function it performs. This assumption has led to the acceptability of patents in the fields of biotechnology and software that cover the individual elements (i.e. particular genes and particular pieces of code). The move from protecting texts to protecting objects was justified by reductionist arguments in biology and control-mode theories in software production. However, increased understanding of biological processes and of the nature of software shows that the mapping between structures and functions is in fact many-to-many, and that assuming a direct and unproblematic link between them leads to inappropriate ownership regimes.

In this paper we explore the conceptual underpinnings of these changes, building up arguments about the nature of the entity which is protected, i.e. ontological considerations (section 2). We propose that ontological arguments for protection are rooted in theories of the relation between the object and its functions (section 3) and discuss the rationale for the protection of texts versus the protection of objects (section 4). Changes in the legal doctrine have come about because of arguments, mainly developed in the scientific and technological community, regarding the relationship between structure and function.

We trace back these conceptual arguments in the life sciences and software (section 5 and 6), and show how the further evolution of scientific understanding should lead us to reconsider them critically. Section 7 explores the implications of our argument for the interactions between science and law. New scientific theories may take some time to establish intellectually and to influence policy makers and the legal profession. When the institutional system is ready to absorb these theories and change legislative tools, however, it may discover that the underlying scientific theory has changed again. In a context where scientific knowledge is continually developing, this is an interesting puzzle for social scientists.

2. Ontological perspectives on intellectual property

The legislation on intellectual property has traditionally been shaped by the consideration of the nature of the product of intellectual activity, i.e. the object to be protected. From this perspective, the distinction between patents, trademarks, copyrights and know-how is firmly rooted in ontological considerations, although they are not framed using this metaphysical language. Only recently has so-called applied ontology started to deal with the nature of specific objects, including artefacts and social objects (Casati & Varzi, 1999; Varzi, 2001; 2005; Bottani & Davies, 2005).

In order to understand the importance of ontological considerations, it is necessary to consider all the legal requirements for the protection of intellectual property. All types of intellectual property protection require *novelty* as a crucial requisite. The reason is clear: things that are not novel do not need protection, or the protection might even worsen the situation, by making rights of use uncertain. The exact meaning of novelty depends on the particular type of protection and is ascertained using different legal and observational techniques (Lévêque & Meniére, 2004). As well as fulfilling the novelty requirement, the European Patent Office requires that patents must also be industrially applicable and must involve an inventive step[1]. A patent must also be sufficiently disclosed, and qualify as patentable subject matter.

The requisite of *industrial use* implies that the invention is replicable (otherwise there is no need for protection) but also implies that it has utility or practical use. A minimal interpretation of this requirement (and one which patent guidelines refer to specifically in respect to the patenting of gene sequences), is that for an invention to have an industrial use it must have a function. Having a function means showing a pattern of behaviour when put under the appropriate conditions. Inventions that do not have a function cannot be protected by patents, but by other means. A piece of art is an invention in the sense of novelty (there is no such a thing as the *Mademoiselles d'Avignon* before Picasso), but is not an invention in the sense of having a function.

The notion of function is an ontological one: to have a function an object must be an artefact (or a living system, as we shall see) but there is no need to demonstrate either that the function is actually implemented, or that it has economic value. It is sufficient that an artefact implements a function, or a set of functions, in a different way, or that it implements a function that no artefact has ever implemented before. From this notion a number of implications arise. First, the distinction between *invention* and *discovery* can be established. An invention is the creation of an object for some intended purpose; a discovery is related to a pre-existent object or explanation of the object. The legislation has traditionally been very firm in maintaining that discoveries, such as scientific laws or theorems, cannot be patented (European Patent Office, 2005, Art. 52). Second, the function of the artefact should be clearly described in the patent application. Third, the industrial use requirement is sufficiently restrictive to avoid any demonstration of the economic value of the object. Industrial use implies potential economic value, not actual value. The existence of a function is a necessary but not sufficient condition for economic value. As a matter of fact, few patents do have economic value, in the precise sense of actually being used. There are many more functions than those selected for actual use in the economy. But since this is not known *ex ante*, the law only requires that the relation between the object and the function is specified.

It is important to characterize the protection given to patents as opposed to trademarks and copyrights as products of intellectual activity. In a sense, all trademarks have the same basic function, i.e. they allow recognition and distinction in the minds of consumers. This function is symbolic: the verbal or iconic content of the trademark must be able to establish a connection with a given product, brand or company. Copyright protects the product of intellectual activity in its visual or textual form. Technically speaking, copyright does not need to have a function, or, alternatively, it has so many that the notion is not interesting. A novel does not have any function in itself, or may have the many functions that come from the interaction with the reader – to make him amused, relaxed, think, feel guilty, cry, laugh, and so on. The author has some intentionality in writing the novel – perhaps she wants to raise awareness of a social problem – but the outcome of the use of the copyright depends very much on the user's reaction. There is no point in assuming any function in a text. In contrast, a function is always implemented if an artefact is properly put to use. A new nutcracker will invariably crack nuts, if an appropriate force is applied in the appropriate place against nuts of ordinary toughness. Although the actual delivery of functions, in many cases, depends on the behaviour of the user, involving social and human considerations, the patent system abstracts from these issues and assumes that use conditions are realized as required.

In sum, for the whole system of protection of intellectual property to work, the relation between the object to be protected and its function must be established. Patents protect artefacts whose function can be predicted as a necessary consequence of their use. The relation between the artefact and the function must be clearly described and the object is protected in view of the logical necessity of its function.

3. A closer look at the relation between objects and functions

3.1 Functional descriptions

Having established the critical role of the relation between objects and functions in patent law, let us explore this issue more closely. The notion of function is crucial for articulating a number of deep issues.[2] Let us start by asking what the relation is between objects (of any kind) and functions. Objects can be described in terms of shape or form, and in terms of materials. Functions can be described as a collection of possibilities, constrained by the constitution of objects. A function is a pattern of behaviour that a given object exhibits under specified conditions, depending on its form and its materials. Functions may be natural or artificial. The function of the heart is to pump blood. This is a legitimate description of a heart and also a legitimate explanation of why the heart is the way it is. Functional explanations are legitimate claims for natural objects of sufficiently large complexity (McLaughlin, 2001). The function of a battery is to store and deliver electric energy, the function of an amortizer is to absorb shocks.

What is the relation between the structure of an object and its functions? Interestingly, this relation is a many-to-many mapping: all structures implement a variety of functions, and each function can in principle be implemented by many structures (Pahl & Weitz, 1984; Sriram, 1997). The mapping between functions and structures is an open-ended process. It has neither logical necessity nor inductive validity. This means that knowledge of the properties of the structure is not logically sufficient to predict function. The only logical implication of properties of the structure is *negative*: we may *exclude* that a given structure may implement a function on the basis of our knowledge about its properties. For example, on the basis of our knowledge of electric conductivity we may exclude that a piece of wood can store electric energy, but from this we cannot derive a complete list of all possible functions that that structure may in fact implement.

3.2 Implications for protection of intellectual property

From this characterization a number of implications can be derived. First, a complete description of an object according to its structure is not sufficient to identify the functions that are the main rationale for legal protection. There must be some argument that establishes a link or mapping between the structure and the function. It is this sort of argument that is the focus of this paper. Here we investigate the evolution of arguments that have been produced to demonstrate the relation between the object of protection and its functions in two seemingly unrelated areas, software and biotechnology. We propose that by examining these arguments we can gain a deeper understanding of the transformation of the intellectual property system in the last two decades.

Based on the above discussion of the functional structure of patent protection, we add another relevant dimension. This refers to the *level of resolution of functions* claimed in the patent application. In general, functions are represented by hierarchical trees. Higher level functions imply the implementation of sub-functions, which in turn are satisfied only if lower level sub-functions are implemented. A functional description of a moderately complex artefact may involve several dozen or a few hundred sub-functions. Usually the implementation of lower level functions has no intrinsic value in itself, but only as part of higher level functions that perhaps may have relevant economic interest.

In general the value of a patent protecting a particular artefact depends on the importance of the implied function for higher level functions, and on the probability of implementing the protected function using different artefacts. As we shall see, both these conditions are hard to verify in software and biotechnological inventions. Nevertheless, a large body of doctrine and legal practice has been elaborated in these two fields based on the demonstration of the linkage between the object to be protected and its assumed function.

4. From protecting a text to protecting an object

4.1 Protecting texts

The starting point of our historical reconstruction can be formulated as follows. For independent reasons, and following different historical paths, there have been two parallel institutional changes in the protection of intellectual property rights in the fields of software and agricultural inventions. Software has been traditionally protected by copyright, following an assimilation of software code to information. In the life sciences, before the extension of patents to biological material, a *sui generis* property right – the plant breeders' right (PBR) – was introduced. Although PBRs apply only to new plant varieties used for agriculture, they are of particular interest for our analysis because the very design of this right is based upon the recognition that living organisms are complex systems. In other words, such a *sui generis* right was created for ontological and epistemological reasons. Furthermore, both copyright and PBRs protect the invention in the form of a text.

While this characterization is made explicit in the legal doctrine for software, it must be clarified for plant varieties. We suggest that the protection of plant varieties bears some analogy with copyright in the sense that both instruments cover a whole entity (and not its parts), they do not protect its intended use, but its intrinsic value, and they can be verified with external observation. This is what protecting a text means: recognizing it by reading the content, acknowledging its intrinsic value, and protecting its integrity. By arguing that plant varieties are protected as texts, we are not denying that they are material objects; instead our aim is to show that seeing them as texts deepens our understanding of their treatment by legislators and judges.

The protection of texts follows some essential rules. First, the protection is assigned to the *text*, not to its elementary parts. In the case of copyright, it is the entire product of inventive activity (a novel, a poem, a song) that is protected, not individual elements such as isolated phrases or words. Copyright infringement can also occur when a "substantial part" of a copyrighted work is reproduced in another work, that is, a sequence of elements such that they can be recognized as produced by the author. While the protection covers both the whole text and its substantial parts, it is clear that authorship cannot be recognised at the level of elementary parts, such as words. In the case of a plant variety, the demonstration of inventiveness follows a typical holistic or morphological procedure: two plant varieties are said to be different if at least a minimum number of external morphological elements are different (Bugos & Kevles, 1992). Moreover, protection of an entity as a text means that the elementary units which form the text are not appropriable; the property right only applies to the original combination (Joly & Hermitte, 1991). A new variety is an original combination of existing elements; the property right granted to the new variety is independent from the property rights granted to existing varieties, even though they are used to obtain it. Hence, PBRs are the perfect example of the protection of invention as a text, where elementary elements (words) are public. This characterization is important because it does not require that the relation between parts and wholes be made explicit. The protection of objects through patents requires the demonstration of the function that they may have with respect to a larger system, or a context of use. The reason for protecting a gear is that, if placed in the appropriate technical system, it delivers the desired behaviour (and hence an overall function with potential value) in a new way. This is not required for a text, in which the relation between parts (words, sentences, paragraphs, chapters) and wholes is presupposed. For the violation of copyright one must demonstrate that the parts copied can be recognized as parts of the original and protected text by any participant. This means that it is not the author that establishes the relation between parts and the whole, or which parts are crucial for the originality of the text.

Second, there is *no need to demonstrate any utility or function*. A text is protected as such, not because of its value. The protection is given to the text because it is believed that it has required an effort and must be compensated.[3] It is not possible to establish the novelty and the industrial value of the text. The demonstration of value cannot be a necessary condition for protection. These properties have had a profound influence on the protection of intellectual property rights (IPRs) in agricultural biotechnology, and in the software industry.

4.2 Protection of plant varieties

In the plant variety case, the above mentioned properties imply that it is not necessary to know the genetic constituents of the variety or to differentiate between varieties at the level of elementary units. The criteria for discriminating between varieties have traditionally been morphological or phenotypical. According to the UPOV Convention[4] a plant variety is protected if it is new, distinct from other varieties of the same species and homogeneous. Distinctness and homogeneity depend on morphological (visible) characters that are different from one species to another. No explanation is needed at the level of genotypes. If we understand the plant variety mechanism as a form of text protection, it becomes clear why it covers the *whole* variety, not its constituent parts, and it does not require a description of the relationship between the whole and the parts. As with texts, there is also no need to demonstrate the utility of the new variety. Finally, it is possible to use a protected plant variety to carry out a hybridization process and develop new varieties.

These features of the protection of intellectual property have important implications for the evolution of industry structure and the nature of innovative activity. The protection of plant varieties does not require any demonstration of difference at the genetic level. This means that a scientific understanding of diversity at the level of genes is not required, and that small firms, farmers and crop producers can participate in the collective process of variety generation and selection, without investing large sums into laboratories for mapping the genetic material. Because of this relatively weak protection regime, the level of profits and rate of concentration in the industry used to be low (except for hybrid seeds which benefited from technical protection, see Joly & Ducos 1993).

It is important to note that when patents and pre-existing breeders' rights conflict, the former prevail. According to Wright (2006) "patents protect the plant breeders' or inventors' rights to control the use, sale, import, and reproduction of plants that have been patented or that incorporate patented material" (p.2). If they patent their plants, breeders can dictate the terms under which these plants can be used and prevent others from using them for breeding. The relevant distinction between patents and PBRs is a taxonomic one, as Straus (2002) explains: "plant varieties, i.e. plant groupings within a single botanical taxon of the lowest known rank, are defined by their whole genome and are protected by plant variety rights. However, plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, may be protected by patent if the relevant invention incorporates only one gene and concerns a grouping wider than a single plant variety" (p.6). As we will see, this hierarchy of protection has deep economic implications.

4.3 Software

In the software case the protection through copyright allowed other inventors, under some conditions, to reverse engineer the code. In particular, in most legislations and international treaties reverse engineering (i.e. reproduction and decompilation of a program) is permitted when necessary for use of the program, for error correction, and for ensuring interoperability. These cases constitute exceptions to the exclusive rights of copyright owners accepted under the fair use doctrine. Of course the doctrine does not cover the case of reverse engineering the code for developing competitive programs, which is forbidden.

The latitude of the fair use doctrine is subject to some controversy in both theory and practice. It is generally accepted that copying all the machine-readable object code in the process of reverse engineering it into human readable format is not permitted, as it is an indication of potential commercial use. But copying portions of the object code for non-commercial purposes is generally accepted by courts under the fair use doctrine.

In practice, decompilation of portions of programs for personal use, training, and subsequent adaptation has traditionally been one of the main sources of technical learning. Such provision greatly contributes to the innovation model of software, which is sequential and incremental rather than isolated and radical. Blind, Edler and Friedenwald (2005) summarize a large literature in stating that software is characterized by "sequentiality, incremental development processes, interoperability, multiple network effects, extremely short innovation cycles, parallel and complementary developments, confusion about authorship of partial inventions (code) (…)" (p. 29). Parallel developments are carried out in multiple locations and it is usually very difficult to establish the state of the art without confusion. Similarly, individual contributions are usually less important than the possibility to capitalize on partial solutions developed by others, without infringing copyright (Bessen & Maskin, 2000). At the same time, the copyright mechanism is a sufficient guarantee for those producers that choose to sustain up-front costs in developing large programs.

4.4 Economic implications of text protection

To summarize our argument so far, the early stages of agricultural biotechnology (particularly plant breeding) and the software industry were greatly favoured by a peculiar regime of protection of intellectual property, based on the assimilation of the invention to a text. This allowed multiple parallel exploration of solutions, and prevented the formation of strong monopolistic power.[5] Given the intrinsic sequential nature of innovation, this greatly favoured innovative processes in both industries.

This situation dramatically changed with the introduction of the notion of patentability of gene sequences and of software. It is now possible for a company to patent particular gene sequences, to prevent other companies from creating new varieties containing these genes, and to prevent farmers from using all varieties that include these sequences.[6] Thus the plant breeding industry, before the emergence of patents, was made up of hundreds of laboratories associated with farmers, which developed new varieties by trial and error. This picture radically changed after 1995, when a wave of mergers and acquisitions among large firms investing in agricultural biotechnology eliminated small breeders from the market and led to a highly concentrated oligopoly (Joly and de Looze 1996, Graff, Rausser and Small, 2003; Graff et al., 2003). A single company, Monsanto, accounts for half of all the field trials of genetically engineered crops in the United States (Wright, 2006). At an international level, these companies focus their commercialisation activity on a few widely used crops (Wright and Pardey, 2006).

It is also possible for a company to patent a software programme and inhibit reverse engineering by other companies. Historically, the software industry in the 1970s and 1980s was comprised of thousands of small developers, with hundreds of suppliers of packaged software (Campbell-Kerry, 2003). The industry went through a consolidation that started in the 1990s (Mowery, 1996) and culminated in the last decade. In the case of software, however, we are not aware of studies showing a direct link between software patentability and industry concentration, as was demonstrated in the agriculture biotechnology industry.

This radical change has had a long history in courts and legal doctrine. We briefly review the parallel history of these changes in order to put forward our main argument. We propose that the two developments, although very different in terms of specific motivations and legal arguments, have a fundamental common thrust. They are based on an argument that has slowly been elaborated in the underlying scientific community (namely, molecular biology and computer science) and has strongly influenced, albeit indirectly, the legal doctrine. This argument, as we will show, establishes the relation between the object of protection and its function, in order to ensure that the monopoly power created by the patent protection appears to be economically and socially acceptable, i.e. welfare-improving.

5. The role of molecular biology in the development of arguments for intellectual property protection in biotechnology

In the case of biotechnology, it is necessary to explain briefly how genes became recognised as potentially patentable inventions. Particularly important was the *Diamond v. Chakrabarty* decision in 1980 in which the US Supreme Court ruled that anything under the sun is patentable, provided that it fulfils the usual criteria for patentability (Kevles, 2002). As they were considered to be “compositions of matter”, microorganisms were ruled eligible for patent protection.

As far as plants are concerned, in 1985 the USPTO took a decision (in Ex Parte Hibberd 227 USPQ 443) which built on the language of Chakrabarty in determining that plants are within the understood meaning of 'manufacture' or 'composition of matter'.[7] Another important development was the first animal patent. The infamous 'oncomouse' patent was issued in April 1988 to Harvard University for mammals genetically engineered to contain a cancer-causing gene (US patent 4,736,866), and it provoked a great deal of public debate about patents on higher organisms. What we see here is a shift from patents on microorganisms to patents on plants, and from patents on plants to patents on animals (Edelman & Hermitte 1988; Kevles 2002). However, behind all these shifts were a series of assumptions rooted in molecular biology: that a whole organism can be reduced to its component parts (Parry, 2004), that these component parts can be patented, and that the most important of these component parts is the gene.[8]

In Chakrabarty it was held that biotechnological inventions were eligible for patent protection because of their analogy with chemical inventions, so the patent offices also treated genes as if they were analogous to chemical compounds (Eisenberg, 2002). According to this chemical analogy, substances that are "isolated and purified" can be patented, if they fulfil the other requirements for patentability, and following this logic, such substances include isolated and purified (i.e. sequenced) genes (see Demaine & Fellmeth 2002; Conley & Makowski 2003). Europe saw similar developments; the Board of Appeal of the European Patent Office (EPO) stated that genes, although present in nature, are patentable under Article 52 (1) of the European Patent Convention if they are isolated and technically processed in such a way that they can be used for the benefit of humankind (T 272/95 of 22 October 2002).

In the mid-1990s, DNA sequencing capacity was growing rapidly, due to the availability of automatic DNA sequencing machines (Cook-Deegan, 1994). The ability to sequence whole genomes led to an exponential increase in the number of DNA-related patent applications filed at the USPTO (Marshall, 1997). Today, more than 2000 whole genes are patented, and there are nearly 50,000 patents on sequences of DNA. These patents claim ownership on a large range of entities containing DNA; from gene fragments to whole genomes (see O'Malley, Bostanci & Calvert, 2005), including everything in between (Nuffield Council, 2002, p. 25). DNA is becoming valued more for its informational content than its material composition (Parry, 2004), and we are even starting to see patent applications that claim DNA sequences in computer-readable form (see Barton, 2002; Eisenberg, 2000; Maschio & Kowalski, 2001; Bostanci & Calvert 2008). However, despite these developments, genes are treated as novel molecules and they are protected through product patents, so any process that uses the molecule is infringing the patent, just as it would with any other chemical compound.

What is particularly interesting about gene patenting is that there is an explicit discussion of the role of function in fulfilling the industrial applicability requirement. The utility requirement (the US equivalent of industrial applicability) became the subject of contention in the early 1990s because of the filing of patents on hundreds of short DNA sequences (Expressed Sequence Tags or ESTs) with no known function (Kevles, 2002). Patents were filed on these gene fragments on the expectation that ESTs would be part of genes coding for proteins, and that these proteins would turn out to be biologically (and, it was hoped, therapeutically) useful. However, arguments were made that ESTs should not be patentable on the grounds that their function was unknown. For example, the US National Research Council (1997) maintained that patenting should move towards 'functional aspects of the genes, rather than being primarily descriptive' (p. 54). Because ESTs were being treated as chemical compounds, a patent on an EST would cover all applications which involved that sequence. For this reason, in a 1997 Statement, the HUGO Intellectual Property Committee urged patent offices such as the USPTO "to strictly limit the claims on ESTs to specified uses since it would be untenable to make all subsequent innovation in which EST sequences would be involved in one way or other dependent on such patents" (Human Genome Organisation, 1997).

In response to these protests, the US Patent and Trademark Office (USPTO) adapted its requirement that a patent be useful in 2001, to say that rather than just demonstrating utility, a gene patent must demonstrate specific, substantial and credible utility. In practice this means that "a patent applicant provide a specific function for a DNA gene sequence" (Kane, 2004 p.721). The significance of these changes spread beyond the USA, since the EPO and the UK Patent Office have adopted very similar standards (Cornish et al., 2003). For example, the European Patent Office (EPO) revised its guidelines in coevolution with the European Commission's Biotechnology Directive, which says that for gene patents it is necessary "to specify which protein or part of a protein is produced or what function it performs" (Directive 98/44/EC, Recital 24). In both these cases, the important point is that the function of a gene must be disclosed in order to fulfil the industrial applicability/utility requirement in gene patents, and in both cases only *one* function needs to be specified. This change was widely believed to have 'solved' the problems presented by the large numbers of patents which had been filed on ESTs and other short segments of DNA sequence (such as SNPs) with no understanding of their function. However, our argument is that this apparently helpful change is actually grounded in an outdated understanding of the ontology of the gene.

We propose that in this process a particular role has been played by the belief that there is an almost exclusive relation between a gene sequence and the coding of a protein (the "one gene, one enzyme" hypothesis first put forward by Beadle and Tatum in 1941). This belief realizes the most ambitious reductionist programme in modern science: explaining the phenomena of life by reducing them to the elementary level of chemistry and physics. The development of the scientific programme of molecular biology is deeply rooted in such a physical and mathematical view of living matter (Kay, 1993; Morange, 1998).

The principle "one gene, one enzyme" led the scientific community to believe that for all phenomena in the organism there should be, somewhere, a DNA sequence ultimately responsible for the observed phenotype. At the same time, it nurtured the belief that for any gene sequence the range of possible functions is restricted, i.e. that one gene codes for only one protein.

It is important to understand the logical implication of this belief in terms of intellectual property. As we have seen, patenting requires that the object of protection implements a function. In conventional inventions the range of functions implemented by the invented object are usually restricted and perfectly specified. Faced with the new field of biotechnological inventions, the economic and legal doctrine had to answer a difficult question: suppose we accept the idea of protecting a gene sequence, what is the function that is actually protected? From the reductionist perspective, the function of a gene sequence is to code for a protein.

This reductionistic strategy has provided judges and legislators with a powerful argument. The "one gene, one enzyme" hypothesis has made it acceptable that protecting the physical elementary entity (i.e. patenting the gene sequence) is:
– logically tenable (it does not violate the distinction between discovery and invention, because the identification of the function of the gene can be claimed as inventive);
– economically acceptable (it protects the invention from abuse from other inventors);
– socially acceptable (the restriction of potential social use of the gene is limited by the definition of the sequence, due to the 'one gene, one enzyme' hypothesis);
– necessary (the only way to protect the invention of useful applications in medicine or agrobiotechnology is to protect the physical entity itself).

The scientific landscape was thrown into turbulence with the publication of the draft sequence of the human genome in 2001. This revealed a number of surprising facts. Notably, the total number of human genes – between 20,000 and 30,000 – was found to be far fewer than the 100,000 expected, according to the famous prediction of Nobel laureate Walter Gilbert. Furthermore, less than three percent of the genome is directly involved in the synthesis of proteins. A large proportion of the DNA, sometimes derogatorily labelled "junk DNA", is not. If the fundamental function of genes is to produce proteins, why does so much of the genome not do this at all? The answer is that much of the genome codes for RNA, previously presumed to be a mere intermediate between DNA and proteins (Gibbs, 2003). In addition to these unexpected functions of 'junk' DNA, a number of discoveries have been made as a consequence of the Human Genome Project that have shed light on the knowledge gained in various areas of biology during the 1990s (see Pearson, 2006). Most importantly, it has been shown that one gene can code for many different proteins, which can be involved in many different biological processes. This situation is problematic for the legal doctrine of patent protection because nothing prevents the protection of one gene from covering a large spectrum of applications, unknown at the outset, providing the assignee with a large monopoly power. One example of this monopolisation of a gene is Human Genome Sciences' (HGS) patent on the CCR5 receptor. It was initially patented because of its role in inflammatory disease, but further research showed that it played a key role in HIV infection. After this discovery, HGS gained rights over this function as well (Nuffield Council, 2002). Another infamous example is the patenting of tests for the detection of the breast cancer susceptibility genes BRCA1 and BRCA2 by the company Myriad Genetics. Since there was no other way of detecting these genes, Myriad Genetics managed to secure a virtual monopoly on the test in the US (Parthasarathy, 2007).[9]

As a result of the complete sequencing of human genome, it is also now possible to develop scientific theories about the relation between the behaviour of living matter at molecular levels of organization and at higher levels of organization, such as cells, tissues and organisms. This makes it possible to depart from the reductionist assumption that explanations at molecular level are sufficient to provide explanations at higher levels (Kitcher, 1984; Waters, 1990; Dupré, 1993). From this perspective, explanations can move back and forth between different levels of organization of living matter, and do not flow uni-directionally from the molecular level up to higher levels (see also Noble, 2006). But if this perspective is correct, then it is clear that the strict relation between structure and function, advocated by reductionists, is lost. Functions can be defined at various levels of organization, but the functions that are particularly worthy of protection are usually those that are defined at higher levels, where there is an effect on tissues or organisms, leading to explanations of diseases. If these complex functions, in practice, cannot be explained only in terms of the constituents of gene sequences, then the entire framework of patent protection must be reconsidered.

We argue that if courts and legislators had anticipated the discoveries of genomics (i.e. that genes are involved in the coding of many proteins and may have incredibly complex functions), they would have considered the matter differently. In fact, for the introduction of patents to be socially and economically acceptable it is necessary to show that the benefits of incentivising innovation are greater than the social loss from granting a monopoly power. The magnitude of the loss depends on the number of innovations that are prevented from occurring because of the monopoly power of the patent owner. It is precisely this argument that was offered to legislators on the basis of the reductionist program in molecular biology: the social loss associated with granting a monopoly will be minimal, insofar as each patented gene sequence is involved in coding for only one protein. If this is the case, the legal requirement of specifying at least one function, but not necessarily all functions, could be considered sufficient for patent protection.

Patenting protects structures insofar as they can be shown to implement a given function, which is to say, exactly because they are inventions. Protecting inventions is logically dependent on the demonstration of a strict linkage between the two descriptions. The central dogma of molecular biology implies that knowledge of a sequence of DNA will give us knowledge of the protein that it produces, and that the function of the DNA sequence is thus to code for the protein. This scientific rhetoric, in a context where patents were seen as essential for achieving the potential of the biotechnology industry, persuaded legal and economic actors that the patent solution was the best way to improve social welfare.

The paradox is that, once this message had been accepted in legal doctrine, it was quickly discovered to be far too simplistic. In practice, this shifting understanding of the ontology of the gene has meant that different patent examiners apply different levels of stringency when trying to assess whether a gene's function has been adequately disclosed in a patent application (Calvert, 2007). And notable commentators, such as Joseph Straus, have suggested that in the light of the unique properties of gene sequences, the scope of protection should be limited to the functions(s) disclosed in the patent application (Straus, 2003).

We even see a few recent examples of courts grappling with new developments in the science, particularly at the European Patent Office. For example, the decision T898/05 attempts to distinguish four different levels of function: structural function, molecular function (biochemical activity), cellular function (function in a cellular process), and biological function (influence of a cellular process in a multicellular organism).[10] However, even though we do see patent practitioners trying to grasp the subtleties of function in this way, this recognition has clearly not been translated into legislation, because it is still the case that only one function needs to be identified to satisfy the utility requirement. Once a patent on a gene has been granted on the basis of one function alone, any other functions that are subsequently discovered will be covered by the existing patent. From the perspective of both the USPTO and the EPO the ontology of the gene remains the same, it is merely a question of refining the law within this context.

6. Doing things with words: how the software text became an object

The debate around the patentability of software has been at least as heated as that concerning biotechnological inventions, with strong arguments on both sides. The emergence of software as an entity protected under IP legislation is the result of a historical process consisting of two key stages: the invention of computers and the invention of high level languages.

Alan Turing's landmark paper in 1937 introduced the idea of a "universal" computation machine which had a physical constitution that could make possible, in principle, any conceivable computation. In other words, Turing clearly had the idea of *software*, as the possibility for a machine to re-program itself without changing its physical internal constitution each time (Moreau, 1984; Bodanis, 2005). In order to realize Turing's intuition, further theoretical steps were needed. John von Neumann, in 1945, proposed an abstract computer architecture in which an internal large reprogrammable memory was the key element (Ceruzzi, 1998; Campbell-Kelly and Aspray, 2004; Rowland, 2006). In turn, this opened the way to the software revolution. In fact, all computable operations that can be performed in a formal language can be translated, subject to constraints of speed, space or sometimes heating, in a physical device that will perform the operations and produce an output. The notion of a Turing machine, therefore, has two implications. First, the two layers of formal operations, written as texts in programming languages, and of physical implementation in electronic circuits, can be developed independently. Second, provided that algorithms are computable, there will always be the possibility to implement them in a machine, whatever its physical details (Wagner, 1998; Moreau, 1984; Davis, 2000).

These achievements opened the way for writing increasingly complex computer programs, in a language that could be immediately translated by the machine into instructions for changing the electrical state of components. Starting in the 1960s a massive effort was made to invent high level languages, that is, languages in which computer instructions could be written in such a way to be readable by human programmers. This move made the development of computer programs independent of the detailed knowledge of the physical elements of a computer and created an enormous opportunity for applications.

In 1969 IBM, pressed by large companies and governments which were worried about its dominance in the mainframe computer industry, agreed to un-bundle the software of its System 360 and sell it separately from the machine. Immediately after this decision, several independent software producers entered the market. The new software industry was born (Steinmuller, 1999; Campbell-Kerry, 2003).

While this rationalization represents the main thrust of computer science and technology in the twentieth century, the cybernetic revolution developed at the same time and yielded important results. Arturo Rosenblueth, Norbert Wiener and Julian Bigelow worked together to invent a mathematical program that was able to predict missile trajectories. In this context the notion of a program was introduced. It enters as a logical implication of the definition of purposeful behaviour as behaviour oriented towards goals. In the context of feedback systems, a program determines the class of responses of the system to the environment

There is a fundamental distinction between the notion of program according to Turing and von Neumann and the one developed by Wiener, Bigelow and Rosenblueth. In the former there is no logical necessity for physical interaction with the environment. In the latter context the program exists insofar as it governs the physical interaction with the environment. Let us label the former a *computation*-mode, the latter a *control*-mode of information. As we shall see, the conceptual distinction between the two perspectives has initially been maintained, but then obliterated in legal doctrine and judicial practice.

We have seen that the emergence of software as a separate industry was spurred by the un-bundling of IBM programs in 1969 and the massive entry into the market of independent software producers. It is against this background that the problem of protection of intellectual property was discussed in the 1970s. If software was to be sold independently from the machine, what would be its regime of protection? Was the patent system applied to computer machines to be extended to the once-bundled software?

For those legal theorists and practitioners who had to be extremely precise in defining the ontology of software as independent from the computer machine the answer was clear: software is a text, not a physical device. It has a life in itself, not as part of the machine. As such, it had to be subject to the classical protection of creative literary work, the copyright (see WIPO, 1998, p. 424). This legal reconstruction is compatible with the notion of computer program developed in the *computation*-mode, where programs only have an effect in the domain of information, not on the physical world outside the computer.

The exclusion of software from the realm of patentable inventions has traditionally been very strict. The Munich Convention formally excluded programs for computers from patentability (EPO, 2005, Art. 52). As a matter of practice, the EPO has traditionally accepted patents in software only if explicitly associated with a physical interface. In 1997 the Board of Appeal of the EPO produced case law which allows algorithms, data structure and data treatment to be patented, as well as the presentation of information. An attempt to codify this in the proposed EC Directive on the Patentability of Computer-implemented Inventions was, however, rejected by the European Parliament in 2005.

The USPTO maintained a negative attitude towards the patentability of software until the early 1980s. An important sentence of the US Federal Circuit in 1994, confirmed and extended in 1998 and 1999, drastically changed this traditional practice and opened the way to patenting software as such. The effects have been massive: in 2002 around 100,000 patents were classified as related to software at USPTO. Since this institutional change in the USA, strong pressures have been put on the European Union to modify the Munich Convention and to admit software patentability.

It is important to reconstruct how the recent inclusion of software was made possible, following the long history of court decisions in the United States. It is our contention that there is an intrinsic logic in the evolution of legal doctrine, but one that is heavily indebted with a particular representation of the relation between the two aspects of software, i.e. software as a text, and software as a device able to produce real effects (functions) in the physical word. This representation, in turn, has extended the protection created for mechanical inventions to information-intensive inventions.

Table 1 summarizes the main arguments proposed by a series of crucial judicial decisions, in the Federal Circuit and at the Supreme Court in the United States.

Table 1 Key steps in judicial decisions related to software patentability in the United States

- **Supreme Court** (SC) *Gottschalk v. Benson* (1972): software non-patentable subject matter, as concatenation of unpatentable mathematical algorithms.
- (SC) *Parker v. Flook* (1978): the simple presence of an algorithm in a patent claim does not prevent the protection of the invention.
- **Federal Circuit** (FC) *In re Freeman* (1979): the patenting of mathematical algorithms (excluded from patentability according to the Benson case), is excluded only if the patent claims cover every use of the algorithm.
- (FC) *In re Walter* (1980): if claims concern a method dedicated entirely to the solution of a mathematical problem without any close relation between the algorithm and the devices used, the invention is not patentable.
- (FC) *In re Abele* (1982): patentability of all claims in which the mathematical algorithm is applied to the physical device of the invention.
- (SC) *Diamond v. Diehr* (1981): software patentable if embedded into a hardware device. Software enabled methods and processes are then patentable.
- (FC) *In re Allappat* (1994): hardware device may be general purpose, since "a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software".
- US Commissioner of Patents *In re Beauregard* (1995): new guidelines on the patenting of software. Software embodied in physical devices is patentable.
- (FC) *State Street Bank & Trust v. Signature Financial Group* (1998): physical structure unnecessary, so long as a process or idea is useful.
- (FC) *AT&T v. Excel Communications* (1999): physical transformation is only one of possible ways to bring about a useful result; patentable software does not need to have an associated physical structure.

Source: our elaboration from Rouvinen and Stankiewicz (2005) and Di Franco and Sanseverino (2004).

It is clear that there is a rationale behind this evolution. The evolution of the US legal system closely follows the intrinsic logic of information-intensive innovation. A pure idea *cannot* be patented, but a pure idea *applied* to a physical device may be patented. But then the question arises: Could the physical device be *general purpose*? The logical answer is positive, because the protected usefulness of the idea (the software) does *not* depend on the specific physical device on which the software runs. This leads to the conclusion that the physical device is unnecessary, because the utility of the software is not dependent on an associated physical structure. Then what is protected is *just* information, not the combination of information *and* physical device. The conclusion is that if one wants to protect that kind of invention, one must be prepared to abolish any distinction.

So the legal argumentation concerned the absence of a distinction between a mechanical device and software that actually produces the same affects as the mechanical device (once applied to a general purpose machine in a control mode). Once this distinction was eliminated, patentability was extended to all kinds of software, including software that does not have an affect on the physical world outside the computer, but is only designed to process information.

It is difficult to deny logical rigour to this argument, once the premises have been accepted. Once the power of software to produce real effects in the physical world has been accepted, the question becomes one of the distinction between the software and the operating machine that brings the information into the world. It has become clear with the evolution of microelectronics and the increase in computing power and speed that it is more efficient to leave the hardware generic and place all the burden of specialization on the software side. General purpose computers have been substituted for dedicated computers in a large number of applications (e.g. flight control and avionics), while software has become increasingly specialized, reaching in some cases extreme performance in non-embedded applications (e.g. real time applications). In a sense, the technological evolution and the emergence of enormously powerful general purpose computers has made problematic the usual distinction between the text of a program and the effects obtained in the physical world by the operation of the program.

However, this division of labour between hardware and software does not eliminate the textual nature of software. The evolution of the legal doctrine has been heavily influenced by the control-mode and has totally neglected the traditional computational-mode of information (see Table 2). And once the patentability of software was accepted as such, it became increasingly easy to see software as a device, rather than a text.

Several negative implications arose from the conceptual shift which followed the patenting of software. Rouvinen and Stankiewicz (2005) have collected a mini-series of cases in which software patents have been granted by the USPTO for general and abstract claims. In all these cases the granting of patents had negative side-effects in terms of private appropriation of crucial elements of collective inventions. Since it is relatively abstract ideas that have been appropriated, the incentives to private inventors have not compensated for the loss of social value. As a matter of fact, in all cases, collective forms of management of IPRs, from patent pooling to standardisation bodies, had to be introduced to remove the danger of lock-in. In sum, applying a notion of information derived from the control-mode to the protection of independent software is a mistake.

Table 2. The two ontological perspectives on software

	Computation-mode	**Control-mode**
Nature of software	A text	A device
Relation of software to environment	No logical necessity for physical interaction with the environment (program only has an effect on the domain of information)	Assumption that the program produces real effects in the physical world
Relationship between structures and functions	The functions produced by the software are independent of their particular physical embodiment (the functions can be multiply realised)	Assumes a narrow relationship between a program and a physical transformation (function), as if logical steps were directly wired into electronic circuits
Ontological assumptions of the IP protection regime	A text, open to continual modification, correction, repair and amelioration by a large community of users-producers	An object, closed and excluded from external intervention
Consequences	Exploiting the open nature of texts can contribute to the social value of software	Private appropriation of crucial elements of collective inventions can have negative side-effects

Source: our elaboration

The neglect of the textual or computational dimension of software depends on a theory that is incorrect. More recent theorizing has shown how wrong such a conceptual shift from computation-mode to control-mode was. The function space of software is defined by all computable operations that can be written in a formal language and executed by a machine. Allowing patentability means assuming a narrow relationship between a particular piece of code and a desired physical transformation. This narrow relationship may be found in embedded software, in which the logical steps of the execution are directly wired into the electronic circuits. But it is quite absent in independent software, even in cases in which the software is highly specialized, because of the textual nature of software.

The textual dimension of software became prominent again after developments such as object-oriented programming, re-usability and modularity, and particularly after the emergence of Open Source. The Open Source paradigm showed that treating software as a text, open to continual modification, repair, correction and amelioration by a large community of users-producers, does better than considering software as an object, perfectly described in a patent but excluded, by definition, from any external intervention. It is not by chance that the whole paradigm of Open Source is based on the legal framework of copyright, while it is radically incompatible with the notion of patentability (McGowan, 2001; Bonaccorsi & Rossi, 2003; Bonaccorsi, Giannangeli & Rossi, 2006). In other words, the Open Source movement challenged the IPR regime change from copyrights to patents. It used the very nature of copyright protection to ensure that code could be distributed openly, while preventing opportunistic agents from exploiting it commercially. It is exactly the protection of software as a text, via copyright, that permits the identification of those that privately appropriate the open source code and lock it into commercially closed licenses. The industrial success of the Open Source movement makes it clear that the assimilation of software to a device, accepted by courts as a compelling argument in favour of patentability, was not logically binding.

In sum, the scientific and technological developments of the 1990s showed that the notion of patentability of software, although plausible from the point of view of the control dimension, seriously neglects the textual dimension of software. In addition, they showed that fully exploiting the open nature of texts (Eco, 1990), as opposed to the closed nature of excludability deriving from patents, can deliver better results.

7. Implications for the interactions between science and law

In the field of IPRs the attitudes of courts and legislators tend to be prudent, even conservative, with respect to structural changes. Proposed changes in the form of legal protection are not accepted rapidly and undergo a long period of discussion and argumentation. This is particularly true for the two changes we are examining here. When plant varieties were subject to the PBR regime under the Paris Convention in 1961 there was no evidence of controversy in the choice of the legal framework. The same can be said after the emergence of software as a separate entity, as a consequence of the unbundling imposed on IBM by the US government in 1969: the adoption of copyright immediately seemed to be a natural and uncontroversial choice. This choice was so deeply embedded into the legal doctrine and practice that, when European governments created a new patent system and drafted the European Patent Convention in 1973, there was no question about placing a formal prohibition on patenting software in this important legal document.

In historical perspective, the fact that in these two fields the regime of protection changed in a relatively short period, and in both cases changed in favour of patents, is an interesting puzzle. Why were these changes introduced, in approximately the same period, after a relatively short legal debate? One possible explanation is political: there were powerful industrial lobbies that promoted a legislative change. In particular, according to some commentators, the pharmaceutical lobby had privileged access to President Reagan's cabinet in the 1980s and was involved in high level policy discussions. Witness the fact that Gerald Mossinghoff, Commissioner of the US Patent and Trademarks Office in 1984, became President of the Pharmaceutical Manufacturers Association by 1985 (Sell, 1995). The role of the pharmaceutical industry in supporting legislative changes and in moving the issue of IPRs onto the agenda of the WTO Uruguay Round has been discussed at length by Angell (2004).

Another explanation is that, in the US system, particularly after the legislation on patents on inventions funded with federal research money (Bayh Dole Act, 1980), the compromise struck between pure science and business was so powerful that it minimized any resistance to the extension of patentability (Slaughter and Leslie, 1997; Kleinman, 2003; Kleinman and Vallas, 2006).

We take a different position here. Legislators and judges are not so susceptible to external pressures. They blend strict legal reasoning with conceptual arguments about the likely outcomes of proposed changes. The precise reconstruction of the steps requires a historical investigation of its own, based on archival work and oral testimonies. However, we argue that the main lines of the most influential arguments are clear enough to justify a conceptual reconstruction.

We have examined the body of argumentation produced by courts over the relevant periods and proposed a conceptualization which is sufficiently rich to capture the main phenomena, but at the same time abstract enough to apply across our two case studies. We have shown how the acceptability of patents in the fields of biotechnology and software has been facilitated by an argument that the mapping between structure and function protected by property rights is unique, or at least highly selective. This reassuring argument was based on a theory of biological functions and a theory of software production that were considered scientifically robust at that time. Both theories relied on the idea that what was being protected was an object, not a text. As we have demonstrated in both our case studies, the move from text to object was dependent on changes in the understanding of the nature of the entity to be protected. In the case of biotechnology, plant breeder's rights protected the organism as a whole, and did not require knowledge of the genetic make-up of the plant. Patenting, however, focused on the gene, which was understood as analogous to a chemical compound. Gene patents relied on an assumption that reflected the dominance of reductionism in molecular biology: that there was a one-to-one relationship between a gene sequence and the coding of a protein, and that the demonstration of such a relationship was sufficient to establish the criterion of function. Developments in our understanding of biological processes have shown that these ontological assumptions should be challenged. A DNA sequence does not necessarily code for a single protein. In fact, the relationship between genes and phenotypes is far more complicated. Higher level biological functions, which are most important economically, can rarely be explained in terms of single gene sequences.[11]

In software, our analysis showed the development of two representations of the nature of a software program: the computation-mode and the control-mode. In the control-mode, software is treated as a device that produces real effects in the physical world. As with the reductionist perspective in biotechnology, where it is assumed that there is a narrow relationship between a DNA sequence and a phenotype, in the control-mode it is assumed that there is a narrow relationship between a particular piece of code and a desired physical transformation. From the control-mode perspective software becomes the kind of thing that can be patented. The computation-mode, in contrast, understands software as a text which operates independently of its particular physical embodiment. In the computation-mode, where software is open to modification and improvement, copyright is more naturally the IP regime of choice.

There are some very interesting parallels to be drawn between software and biotechnology. In both cases we see the instantiation of a physical function, but this does not mean that an identifiable software program/DNA sequence underlies that particular function. In both, it is clear that the mapping between structures and functions is many-to-many. If we assume that there is a direct and unproblematic link between structures and functions this can lead to inappropriate ownership regimes.

Reductionist theories in biotechnology and control-mode theories in software took some time before becoming established and respected in the scientific community and becoming the standard of reference for legislators and judges. After a while, they succeeded in influencing their way of thinking, producing a real policy effect. Now we understand that these theories are wrong, or at least severely distorted. But meanwhile the legal framework has changed. This is important, because in newly emerging fields, due to the relative lack of experience of the real effects of IPR protection, there may be the danger of granting excess protection, inhibiting innovation.

Our aim in this paper has been to draw attention to long-term underlying scientific theories that may subtly but strongly influence the causal reasoning of various actors in the innovation system. Such a level of analysis is rarely taken into consideration in the innovation literature, but it offers a useful unifying perspective. There is a need for further investigation of the ways in which the law adapts to new entities resulting from techno-scientific developments. Clearly, our analysis shows that there is more to this matter than the gap between science and law that is often pointed to in the literature (Jasanoff, 2008). The issue is how to produce legal norms and practices in contexts of changing and uncertain knowledge. Furthermore, we have shown here that the extension of patents to new entities is not just driven by the production of new knowledge but that it is also grounded in metaphysics –

in ideas about the ontology of the objects to be protected – and that this ontology is imported from mechanical inventions. The nature of knowledge and of the (often implicit) metaphysics underlying legal developments deserves more attention from the social sciences. On the political level, institutions that have a mandate to create and interpret the law should be more explicit about the ontological assumptions that they draw upon when making their decisions.

[1] The requirements for patentability in the US are similar but use the terminology of 'utility' instead of industrial applicability and 'non-obviousness' in place of inventive step.

[2] The notion of function has a troubled history in logic and philosophy of science (see Bonaccorsi, Apreda & Fantoni, 2009; Bonaccorsi, 2011). Its logical validity was put in doubt by such eminent philosophers as Hempel in the 1950s, and the whole issue became rapidly obsolete. Because functional explanations can appear to be bound up with teleology, philosophy of science preferred to deal with notions of causality and causal explanation, rather than functional explanation (McLaughlin, 2001). Wright's 1973 article is considered to have re-established philosophical reflection on functions, which is now thriving, and analyses both biological and artificial worlds (see Cummins, 1975; Millikan, 1984; Lewens, 2004; Thomasson, 2007; Krohs & Kroes, 2009).

[3] More deeply, the constitutional foundation of copyright legislation can be found in the distinction between idea and expression: while the author has the monopoly on the expression, the underlying idea must be in the public domain and have free circulation, for the benefit of a democratic society.

[4] UPOV (Union pour la Protection des Obtentions Végétales) was first signed in 1961 and further revised in 1991 to include the applications of new biotechnologies (gene transfer, molecular probes, marker-assisted selection etc.), while keeping within the original spirit (www.upov.int).

[5] Of course, Microsoft is an important exception. However, its monopolistic power is less due to copyright protection than to its ability to establish a standard in the layer of the software architecture that governs all other layers through compatibility constraints.

[6] In the US, plant varieties *per se* may be protected by patents, which is not the case in Europe.

[7] This understanding was confirmed 16 years later by the Supreme Court decision J.E.M AG Supply v. Pioneer Hi-Bred International, Inc. The situation is quite different in Europe, however, where plant *varieties* as such are excluded from patentability (European Patent Convention, art. 53a); this position was confirmed in the 98/44/EC Directive on the legal protection of biotechnological inventions.

[8] In contrast to these reductionistic arguments, widely accepted in the US, Jasanoff (2005) has shown how justices in Canada in 2002 used anti-reductionist arguments to argue against the patenting of *Oncomouse*: "Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed. (…) The fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualize higher life forms as mere "composition(s) of matter"" (Jasanoff, 2005, p. 212).

[9] In a recent and surprising ruling United States District Court Judge Sweet deemed these patents invalid on the grounds that the patented genes should be considered products of nature. He argued that DNA performs the same function in nature as it does in isolated and purified form, and that this function is to code for a protein. In this way, the ruling does not acknowledge the multi-functionality of DNA that we are arguing for here. However, Judge Sweet also maintained that DNA should not be thought of as a chemical, but as "the physical embodiment of biological information distinct in its essential characteristics from any other chemical found in nature" (*Association for Molecular Pathology v. USPTO* 2010 p.3). If DNA is considered as informational rather than chemical then the link between structure and function is problematised.

[10] The main focus of the T898/05 decision, which we do not have space to discuss here, concerned whether computer-assisted identification of the putative function of a gene was adequate to establish function, or whether wet science was required.

[11] Although we are critical of patents on biological material, we do not think that copyright is the clear alternative. The idea that the products of genetically engineering should be protected through copyright has been made on many occasions. For example, Kayton (1982) has argued that the category of "literary work" explicitly mentioned in the US Copyright Act should apply to genetic materials. The inventor of gene shuffling, Stemmer (2002), used this approach for his own invention. However, other authors have warned that "copyright protection of biotechnological innovation would accentuate this basic tension between the exclusive rights granted to authors as incentives to produce, and the mandate to promote the arts and sciences, by dissemination of those works" (Hogle, 1990, p.14). The suggestion to move from patents to copyright in biotechnology has been proposed again quite recently (Holman, 2010), interestingly on the basis of an analogy between software and synthetic biology. We do not have space to do justice to this topic here, aside from making the point that these authors have focused their discussion on the DNA sequence, and our argument throughout this paper has been that it is problematic to assume that an organism can be reduced to its DNA sequence alone.

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